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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,916	07/09/2001	Hiroshi Shiku	P20854	1184
7055	7590	04/21/2004	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			EWOLDT, GERALD R	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,916

Applicant(s)

SHIKU ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Notice of Non-Responsive Amendment, mailed 4/09/04 is vacated. An Action on the Merits follows.

2. Newly amended Claims 1-12 and newly submitted Claims 15-20 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to cells capable of inducing cellular immunity, i.e., antigen presenting cells APCs (and methods of producing said cells). The invention under examination is a method for inducing cellular immunity (and previously the effector cells of cellular immunity, CTL).

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claims 1-12 and 15-20 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 13 and 14 are being acted upon.

4. In view of Applicant's amendment (which necessitates the withdrawal of Claims 1-12 and 15-20), filed 1/13/04, the previous rejections under the second paragraph of 35 U.S.C. 112 and 35 U.S.C. 102 have been withdrawn.

5. Applicant has requested a reconsideration of the IDS filed 3/03/01. Applicant is advised that the Form 1449 for the consideration of abstracts of WO98/09650 and WO92/04887 has been initialed. Applicant is advised that absent certified translations, the Japanese language documents will not be considered except as previously indicated on the Form 1449.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 13 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nestle et al. (1998, IDS) in view of Jiang et al. (1995, of record).

As set forth previously,
Nestle et al. teaches a method for inducing cellular immunity comprising isolating an APC, reacting said APC with a tumor antigen, and returning the resulting cell to the living body by parenteral administration (see particularly Methods, page 331, column 2 - page 332, column 1).

The reference teaching differs from the claimed invention only in that it does not teach the reaction of the APC with a complex comprising a hydrophobized polysaccharide.

Jiang et al. teaches that the dendritic cell (DC) homolog of the macrophage mannose receptor (DEC-205) can facilitate a 100-fold increase in the uptake and presentation of antigen by a DC (see particularly page 154, Figure 4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method for inducing cellular immunity comprising isolating an APC, reacting said APC with a tumor antigen, and returning the resulting cell to the living body by parenteral administration, as taught by Nestle et al., including a hydrophobized polysaccharide complex (such as mannan) in the reacting of the antigen with the APC. One of ordinary skill in the art at the time of the invention would have been motivated to add a mannan complex to the reaction because said addition would have been expected to increase the uptake and presentation by the DC, given the teachings of Jiang et al. that activation of the DC homolog of the macrophage mannose receptor (DEC-205) can facilitate a 100-fold increase in the uptake and presentation of antigen by a DC.

Applicant's arguments, filed 1/13/04, have been fully considered but they are not persuasive. Applicant begins by reiterating the rejection and reiterating the claims. Applicant then asserts "Applicants respectfully submit that one having ordinary skill in the art would not have been motivated to combine the disclosures of Nestle and Jiang. However, even if for the sake of argument, the disclosures were combined, Applicants note that neither of Nestle nor Jiang discloses reacting a complex comprising a hydrophobized polysaccharide and an antigen with the antigen-presenting cell. Therefore, no combination of Nestle and Jiang would include a hydrophobized polysaccharide-antigen complex. For example, Jiang teaches that antigen presenting functions of dendritic cells is associated with the high-level expression of a specific receptor, DEC-205. Nestle teaches that the *in vivo* creation of an antigen-dendritic

cell yields an increase in the immune response of inoculated patients. The combination of these two documents would at most lead to an antigen-dendritic cell overexpressing DEC-205, and not the currently claimed method including a hydrophobized polysaccharide-antigen-cell complex."

Applicant is advised that in view of the prior art, sound scientific reasoning renders the method of the instant claims obvious. Nestle et al. teaches loading APC (that had to have been previously isolated from a living body) with tumor antigens for return to a patient (living body) for the induction of CTLs (cellular immunity). Jiang et al. teaches a way to facilitate the loading of APC, i.e., the use of a hydrophobized polysaccharide. Accordingly, the combined references comprise an improved method and render the method of the instant claims obvious.

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action:

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

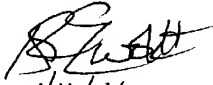
11. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications

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is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

G.R. Ewoldt, Ph.D.
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4/14/04
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER